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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,266	05/23/2000	William G. Johnson	601-1-057N	4282

7590 04/23/2002

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/23/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,266

Applicant(s)

JOHNSON ET AL.

Examiner

Marjorie Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 30-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,8,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

Applicant's election with traverse of Group IV, claims 19-29 in Paper No. 7, filed 1/23/02, is acknowledged. The traversal is on the ground(s) that a search for Groups I and IV, as the Groups do not defined compositions with properties so distinct as to warrant separate examination and a search for both Groups would not be an undue burden on the examiner. This is not found persuasive because (a) the claims of Groups I and IV are directed to methods, not compositions; and (b) the methods of each Group recite different steps and are directed to different results. While the method of Group IV may use the dataset generated by the method of Group I, the dataset created as part of the method of Group IV is NOT limited to be one generated by the method of Group I. The datasets of Groups I and IV may, in fact, be different datasets as the dataset of Group I necessarily comprises data from multiple human subjects which are not the same as the subjects whose genetic data is added to the dataset of Group IV. In addition, a search for any Group requires a search of nonpatent literature and foreign patents as well as a search of US patents. As the methods of Groups I and IV recite different limitations requiring different searches and as multiple databases must be searched for any one Group, the examiner maintains that it would be an undue burden to search for more than one Group. It is noted that applicant admits on page 3 of the response filed 1/23/02 that the Groups are patentably distinct. The current examiner does not agree with the species election applied to Group IV by the previous examiner, therefore all species elections are withdrawn as they apply to the claims of Group IV.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-19 and 30-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Drawings

The drawings have been objected to by the draftsman as set forth in Form PTO 948.

Information Disclosure Statement

The information disclosure statement filed 6/15/00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but not all of the references therein have been considered. Reference AO, to CHEN et al., is also listed on the IDS filed 2/15/02. To avoid duplication, the CHEN reference has been considered as part of the IDS filed 2/15/02, and has been crossed out on the IDS filed 6/15/00. References AK and BF, to BRIXEY et al. and GRICE et al., respectively, were not received with the IDS and are not found elsewhere in the file. Two references not cited in the IDS were found with the group of references filed. These references do not appear to be relevant to the instant claims. The correct *number* of references were

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therefore received with the IDS, but two of the references were apparently included in error, and two "correct" references were omitted. The references which were not submitted have been crossed out to indicate nonconsideration. All references which have been considered are initialed. The examiner's signature indicates that only the initialed references have been considered.

The IDS's filed 12/3/01 (paper #5), 10/23/01 (paper #6), 2/15/02 (paper #8), and 3/11/02 (paper #9) have all been considered in full.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 34. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

Claim 22 limits a binary linear regression to be preformed by an "SAS system." The specification does not describe an "SAS system" anywhere. The specification discloses the definition of several terms on pages 19-22; "SAS" is not defined therein. The specification exemplifies data analysis on pages 78-84, and specifically discloses "SAS" output and datafiles on pages 78 and 81-84; again, "SAS" is not defined, nor does the specification describe how the output and datafiles were generated (e.g. such that one skilled in the art would be able to determine what an "SAS system" is). As an "SAS system" is not fully and clearly described anywhere in the specification, claims 22-29 are rejected for lack of written description. Applicant is reminded that additions to the specification which are not fully supported by the originally filed specification and/or claims may be considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "the SAS system" in line 2. There is insufficient antecedent basis for this limitation in the claim, therefore the claim is indefinite

Claim 22 recites the "SAS system" in line 2. An "SAS system" is not defined or described by the specification (see above) and it is unclear what the initials "SAS" stand for or what an "SAS system" is, therefore the claim is indefinite. As the limitation intended by applicant is so unclear as to make a search impossible, claims 22-29 will not be further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WHITEHEAD (QJM (1995), vol. 88 (11), pp. 763-766) in view of WEINBERG et al. (Am J. Hum. Genet. (4/1998) vol. 62 (4), pp. 969-978) and CHATKUPT et al. (Am. J. Med. Genet. (1992) vol. 44 (4), pp. 508-512).

Claim 19 recites a method of estimating the probability of a an individual to have offspring which develop a developmental disorder comprising collecting a biological sample containing nucleic acids or protein from one or more subjects, analyzing the nucleic acids or proteins to generate a genotype of alleles associated with folate, pyridoxine and/or cobalamin metabolism, adding the resultant dataset(s) from each subject to a reference dataset, formulating a model based on the subject dataset(s), then analyzing the combined dataset by binary logistic regression to determine a predicted probability for an individual (or subject) to have offspring which develop a developmental disorder and to estimate a genetic and environmental susceptibility of the individual toward having offspring which develop a developmental disorder. Claim 20 limits the model to an added step of modification and choice of a best fit. Claim 21 recites testing the model for goodness of fit.

WHITEHEAD teaches a method of genetic screening to identify people at risk for having children with neural tube defects (NTDs) wherein blood is obtained from subjects with NTDs and from normal subjects, genotyping of DNA is performed for samples from both NTD and normal subjects, and a model is formulated to determine the probability

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of a parent at risk for having children with NTDs; specifically, to identify mothers who require folic acid supplementation (abstract, pp. 764-765). WHITEHEAD teaches logistic regression of his data (p 764) and teaches that genetic-environmental interactions affect the model (p. 765). WHITEHEAD does not teach modifying the model or testing for goodness of fit.

WEINBERG teaches adjusting models by relating disease genes to fetal and parental characteristics (imprinting) wherein genetic variables are adjusted and the model is tested for goodness of fit (pages 975-976).

CHATKUPT teaches parental genomic imprinting in spina bifida; an NTD; (abstract and p. 511).

It would have been obvious to one of ordinary skill in the art at the time of invention to have included WEINBERG's adjustment and goodness of fit analysis for genomic imprinting in the method of WHITEHEAD where the motivation would have been to include both environmental and genetic factors in the model, as suggested by the teaching of WHITEHEAD for inclusion of genetic-environmental interactions, specifically with regard to maternal diet, in his method, and the teaching of CHATKUPT that parental imprinting (i.e. an "environmental" factor) is involved in development of spina bifida.

Conclusion

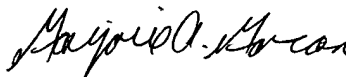
Claims 19-29 are rejected; claims 1-18 and 30-47 are withdrawn.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.


Marjorie A. Moran
Examiner
Art Unit 1631

April 22, 2002

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.